

Remarks

In the Office Action under reply, claims 1-9, 11-44, 91, 93-103, 107 and 108 were examined. Claim 109 has been withdrawn by the Examiner as directed to a non-elected invention. The remaining pending claims stand rejected as follows:

- (1) Claims 1-9, 11-44, 91, 93-103, 107 and 108 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement;
- (2) Claims 1-9, 11-44, 91, 93-103, 107 and 108 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite;
- (3) Claims 1-9, 11-44, 91, 93-103, 107 and 108 stand rejected under 35 U.S.C. §101, since the claimed invention is directed to non-statutory subject matter;
- (4) Claims 1, 5-9, 11-17, 21, 22, 30-32, 37-43, 91, 96-103, 107 and 108 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,342,349 to Virtanen;
- (5) Claims 2-4 and 33-36 stand rejected under 35 U.S.C. §103(a) as obvious over Virtanen in view of U.S. Patent No. 6,395,562 to Hammock et al. ("Hammock"); and
- (6) Claims 1, 2-9, 11-13, 18-27, 31, 32, 37, 39, 40, 42-44, 91, and 93-95 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,284,459 to Nova et al. ("Nova") in view of Virtanen.

The foregoing rejections are addressed partly by the amendments to the claims and are traversed for the reasons discussed below.

Amendments to the Claims:

By the foregoing amendments, independent claim 1 has been amended to recite that "the target moiety is a substance that induces a detectable response signal by the probe moieties" and interaction between the target moiety and a probe moiety results in the detectable response signal from the site of the probe moiety interacting with the target moiety. Support for this amendment may be found in the specification at least at page 35, line 16 et seq., in original claim 58, in the discussion at page 24, line 3 et seq. concerning probe and target moieties, and in the discussion beginning at page 36, line 2 relating to the application of a substance (i.e., a target moiety) that induces a response from the moieties attached to the substrate (i.e., the probe moieties).

Claims 1, 13-17, 21, 22 and 107 have also been amended to replace the phrase "detectable/readable" with "detectable or readable" as supported at least by the specification at page 36, line 4 ("responses may be measured or detected"), as well as the use of the terms "readable" and "detectable" throughout the specification.

Claim 11 has been amended to recite "no less than 1 megabyte of data" and, due to the removal of the term "about" in claim 11, claim 12 has been amended to depend from claim 103.

Claims 24-26 have been amended to recite in claim 24 that the attached probe moieties are protected "by a covering layer that covers the attached probe moieties," as supported by the specification at least at page 20, lines 16-17 and by original claim 25, and, in claim 25, that the protective layer encases the attached probe moieties, as supported by the specification at page 22, line 17 et seq.

Claims 27 and 28 have been amended to clarify that the protective layer may allow the passage therethrough of matter "or radiation," such as electromagnetic radiation according to claim 28.

Claims 33-37 have also been amended to remove the term "about" and new claim 110 added to provide claims coverage for the device of claim 30, wherein the array comprises "about 5,000 probe moieties per square centimeter of substrate surface."

Claim 36 has been further amended to correct a typographical error.

Accordingly no new matter has been introduced into the claims.

Status of the Claims:

Claims 1-9, 11-44, 91, 93-103, and 107-110 are pending. Claims 1, 13-17, 21, 22, and 107 are currently amended and new claim 110 added. Claims 10, 45-90, 92, and 104-106 are canceled.

The Outstanding Rejections:

Claims 1-9, 11-44, 91, 93-103, 107 and 108 stand rejected over the references and for the reasons noted above.

In consideration of applicants' amendments and arguments submitted with the response filed December 22, 2003, the present Office Action indicates that the art rejections based on Virtanen, Virtanen in view of Hammock, and Nova in view of Virtanen have been maintained.

In addition, new rejections were entered by the Examiner under 35 U.S.C. §112, first and second paragraphs, and under 35 U.S.C. §101.

Briefly, applicants submit that the outstanding rejections should either be withdrawn for the reasons that follow or are rendered moot by the amendments to the claims. As may be noted, the pending claims relate to a device for performing an experiment with a target moiety in which the device is comprised of a substrate having a plurality of probe moieties each attached to a designated site on a surface thereof and containing machine-readable information relating to the probe and/or target moieties. Unlike technologies described in the cited references, applicants' device includes a source of a target moiety that induces a detectable response signal by the probe moieties from the site of the probe moiety interacting with the target moiety such that an interaction between the target moiety and a probe moiety results in a detectable response signal that has the same detectable or readable form as the data signal representing the machine-readable information.

Rejection Under 35 U.S.C. §112, First Paragraph:

Claims 1-9, 11-44, 91, 93-103, 107 and 108 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection for at least the following reasons.

In the Office Action, it is indicated that the addition of the claim element "source of the target moiety" to claim 1 represents new matter since the specification fails to define or provide any disclosure to support this language. Applicants respectfully disagree.

While the phrase "source of the target moiety" is not specifically mentioned in the specification, applicants submit that the specification nonetheless does provide clear support for the use of this language in the claims. For example, the specification clearly refers to probe (i.e. molecular) moieties attached to substrates and target moieties from a substance that induces a response by the molecular (probe) moieties. See generally page 4, line 2 et seq. in which the substrate is described as having a plurality of molecular moieties attached to the substrate surface and page 6, lines 1-4 for the reference to Fig. 5C that "illustrates the ejection of a droplet from a second fluid containing a second molecular moiety adapted for attachment to the first moiety" on the substrate surface.

In addition, at page 12, line 22, applicants refer to a "probe and target" that is further described at page 24, lines 4-5 in terms of oligo- and nucleotidic moieties in which "the inventive device may contain attached oligonucleotides that serve as probes to assess whether target nucleotidic moieties are present in a sample." Example 3 of applicants' specification also provides information concerning the attachment of target nucleotidic moieties from a sample to probe oligonucleotidic moieties attached to a substrate surface.

Still further, at page 27, line 10 et seq., applicants provide a discussion concerning the ejection of fluids from a plurality of reservoirs and at page 29, line 11 to page 30, line 19, in reference to Figs. 5A to 5C, applicants describe the ejection of a first molecular (probe) moiety from a reservoir 113 (see Fig. 5A) onto a disk substrate followed by the ejection of a second molecular (target) moiety from a second reservoir 115 (see Fig. 5C) onto the disk at the site where the first moiety was ejected onto the disk. The second moiety is further described as adapted for attachment to the first moiety.

From this information, the skilled artisan would appreciate that applicants have described the use of probe and target moieties, that the first (probe) moiety is attached to a substrate surface and that the second (target) moiety is thereafter applied to the substrate at the location where the first moiety is attached to the substrate surface. Also, given the disclosure of the application of the second (target) moiety from a "sample" and from a second "reservoir," it would be understood that adequate support for the use of the generic term "source" exists. As such, the claim element "source of a target moiety" is supported for the skilled artisan by the information applicants have provided in their specification.

For at least the foregoing reasons, applicants submit that the skilled artisan would understand that the claimed invention is supported by their specification. Accordingly, withdrawal of the first paragraph rejection is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph:

Claims 1-9, 11-44, 91, 93-103, 107 and 108 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. Applicants respectfully traverse this rejection for at least the following reasons.

In the Action, claims 1-9, 11-44, 91, 93-103, 107 and 108, and, separately, claims 13-17, 21, 22 and 107, are cited as being unclear due to the use of a slash mark ("/") between "detectable" and "readable."

By the foregoing amendment, claims 1, 13-17, 21, 22 and 107 have been amended to substitute the wording "detectable or readable" for the phrase "detectable/readable." While applicants do not consider that such an amendment should be necessary for the skilled artisan to understand the meaning of the claims language, this amendment has nonetheless been submitted in the interest of expediting the prosecution. Applicants further note that the alternative recitation of "detectable or readable" does not exclude the combination of "detectable and readable" from being within the scope of the claims by virtue of the open language of the claims due to the use of the term "comprising."

As concerns, claims 11, 12, and 33-37, the phrases "no less than about" and "at least about" have been cited as unclear. While applicants do not agree with the comments provided in the Action for the reasons noted in their previous responses, by the foregoing amendments, these phrases have been amended to remove the term "about." As such, the rejection of these claims is moot.

Applicants further note that the scope of the claims has not been changed, however, since the amendments to claims 11 and 12, as well as the amendments to claims 33-37 coupled with the addition of new claim 110, provide the same coverage.

Applicants respectfully submit that the claims are clear within the meaning of the second paragraph. Withdrawal of the indefiniteness rejection is requested.

Rejection Under 35 U.S.C. §101:

Claims 1-9, 11-44, 91, 93-103, 107 and 108 stand rejected under 35 U.S.C. §101, since the claimed invention is directed to non-statutory subject matter. Applicants respectfully traverse this rejection for at least the following reasons.

In the Office Action, it is asserted that the recitation "machine-readable information relating to the probe and/or target moieties," as recited in claim 1, represents merely descriptive information that is not "functionally interrelated with the substrate" such that the information is "non-functional descriptive material." In making this rejection, the Examiner has relied on the

information provided in the MPEP as well as certain legal precedents issued by the courts to conclude that the claimed device represents non-statutory subject matter. Applicants disagree.

Notwithstanding the reasoning provided in the Office Action, Applicants respectfully submit that the claimed invention is statutory subject matter and is not properly characterized as "merely descriptive" or "non-functional" information according to the legal precedents cited in the Office Action. Instead, as may be noted from the language of claim 1, applicants' invention, as claimed, is clearly directed to "a device for performing an experiment with a target moiety," the device comprising "a substrate having a plurality of probe moieties each attached to a designated site on a surface thereof" and "a source of the target moiety" (emphasis added). In addition, certain characteristics of the device are claimed such as the functional relationship between the target and probe moieties, the provision that a detectable response signal results from the interaction between these moieties, and the provision that the response signal is in the same detectable or readable form as the data signal that represents the machine-readable information contained on the substrate relating to the probe and/or target moieties. As should be understood, the claimed device is not "directed to" descriptive information since a device is claimed, not merely the information that forms part of the claimed device.

Applicants further note that the mere inclusion of information as part of the claimed device does not render the entire claimed device non-statutory. As noted in MPEP §2106 IVB2a ("Statutory Product Claims," page 2100-14, 8th ed.), statutory subject matter includes products such as machines (a machine being "a concrete thing, consisting of parts or of certain devices and combinations of devices," quoting *Burr v. Duryee*, 68 U.S. 1 (1. Wall.) 53, 570 (1868)). Further, as stated in this section of the MPEP, "[i]f a claim defines a useful machine or manufacture by identifying the physical structure of the machine or manufacture in terms of its hardware or hardware and software combination, it defines a statutory product" (MPEP §2106 IVB2a, page 2100-14, 8th ed., citing *In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994) and *In re Warmerdam*, 33 F.3d 1354, 1361-62 (Fed. Cir. 1994) at page 2100-14).

In the case of applicants' claims, the claimed device is clearly more than simply information by itself and, in accordance with the discussion provided in the MPEP (as noted above) is statutory subject matter regardless of whether or not such information forms part of the claimed device.

For at least the foregoing reasons, applicants respectfully request that the rejection under 35 U.S.C. §101 be withdrawn.

The 35 U.S.C. §102(e) Rejection over Virtanen:

Claims 1, 5-9, 11-17, 21, 22, 30-32, 37-43, 45, 47-49, 91, 92, and 96-102 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,342,349 to Virtanen. Applicants respectfully traverse this rejection for at least the following reasons.

In the Office Action, it is stated that Virtanen discloses a device comprising a substrate having a plurality of molecular moieties attached thereto and containing machine-readable information relating to the moieties, wherein the information is physically associated with the substrate. It is further stated that the sources disclosed by Virtanen are encompassed by applicants' claims because the claimed "source" is broadly claimed. A number of additional specific citations are also provided for the rejected dependent claims.

Applicants respectfully submit that the Office Action fails to set forth a proper basis for rejection of the claims under 35 U.S.C. §102 since each and every element of the claims is not disclosed by Virtanen. As noted in *In re Spada*, 15 USPQ2d 1655 (Fed. Cir. 1990), unless there is "identity of invention," such that all claim elements are disclosed in a single reference, there can be no anticipation under 35 U.S.C. §102.

As amended, independent claim 1 recites that the "target moiety is a substance that induces a detectable response signal by the probe moieties and interaction between the target moiety and a probe moiety results in the detectable response signal from the site of the probe moiety interacting with the target moiety." Virtanen fails to clearly disclose or suggest such a feature to support a §102 rejection.

More specifically, Virtanen describes a number of embodiments in which analyte-specific signal elements are disposed on a substrate. These signal elements are further described (either generally or according to certain embodiments) as being cleavable and having a signal responsive moiety (e.g., a gold microsphere) at a signal responsive end of the cleavable signal element. Contacting of the cleavable signal element with an analyte from a sample constrains the cleavable signal element such that non-constrained cleavable signal elements are cleaved during later processing. See, e.g., the Summary at columns 5-7 and column 14, lines 1-6.

According to Virtanen, the analyte essentially functions to prevent the loss of the signal responsive moiety by allowing the signal responsive moiety to remain attached to the substrate. In these embodiments, Virtanen's signal responsive moiety (such as a gold microsphere) is initially attached to the substrate and remains attached through the linkage provided by the analyte following cleavage processing.

By comparison, according to applicants' claims, the target moiety "induces a detectable response signal by the probe moieties." In this regard, the term "induce" should be understood in terms of its ordinary meaning, namely that the target moiety "causes" or "produces" the response signal by attachment to the probe moiety, rather than simply preventing loss of the signal according to Virtanen by allowing the signal moiety to remain attached to the substrate following cleavage. Unlike Virtanen, in which the signal moiety is already part of the probe moiety attached to the substrate such that the signal moiety is simply prevented from being lost during cleavage processing, applicants' target moiety induces a detectable response signal. For this reason, applicants submit that the device of claim 1 is different from the device described by Virtanen.

Accordingly, Virtanen does not anticipate applicants' claims within the meaning of 35 U.S.C. §102. Withdrawal of the §102 rejection is respectfully requested.

The 35 U.S.C. §103(a) Rejection over Virtanen in view of Hammock:

Claims 2-4 and 33-36 stand rejected under 35 U.S.C. §103(a) as obvious over Virtanen in view of Hammock. Applicants respectfully traverse this rejection for at least the following reasons.

In the Office Action, it is again stated that Virtanen discloses a device comprising a substrate having a plurality of molecular moieties attached thereto and containing machine-readable information relating to the moieties, wherein the information is physically associated with the substrate. It is further stated that Virtanen discloses a source of a target moiety and that these sources are encompassed by applicants' claims because the claimed "source" is broadly claimed. Regarding claims 2-4, it is stated that the elements of these claims are nonfunctional and do not distinguish over the prior art. Regarding claims 33-36, it is acknowledged that Virtanen does not disclose the density of moieties on the surface; however, Hammock is relied

upon to suggest the claimed moiety density (citing column 5, lines 60-65, and claim 7 of Hammock).

Applicants respectfully submit that the Office Action fails to set forth a proper basis for rejection of the claims under 35 U.S.C. §103 at least for the reason that Hammock clearly fails to cure the deficiencies of Virtanen.

Applicants note that claims 2-4 and 33-36 depend from claim 1 and are therefore allowable over Virtanen, as well as the combination of Virtanen with Hammock, for the reasons noted above concerning the rejection based solely on Virtanen. In addition, Hammock fails to remedy the deficiencies noted above in Virtanen such that claims 2-4 and 33-36 are allowable for this reason as well.

More particularly, applicants note that Hammock fails to provide any disclosure relating to a device comprising a substrate having probe moieties attached thereto and a source of a target moiety wherein the "target moiety is a substance that induces a detectable response signal by the probe moieties and interaction between the target moiety and a probe moiety results in the detectable response signal from the site of the probe moiety interacting with the target moiety." Hammock also fails to provide any information to suggest the desirability of modifying Virtanen to include applicants' claimed feature. Instead, the disclosure in Hammock relating to the attachment of moieties to a substrate surface is limited to ordinary fluid dispensing techniques such as ink-jet printing and pipetting. See column 3, lines 19-42.

For at least the foregoing reasons, applicants request withdrawal of the rejection based on the combination of Virtanen and Hammock.

The 35 U.S.C. §103(a) Rejection over Nova in view of Virtanen:

Claims 1, 2-9, 11-13, 18-27, 31, 32, 37, 39, 40, 42-44, 91 and 93-95 stand rejected under 35 U.S.C. §103(a) as obvious over Nova in view of Virtanen. Applicants respectfully traverse this rejection for at least the following reasons.

In the Office Action, it is asserted that Nova discloses a device comprising a substrate having a plurality of molecular moieties attached to a surface and containing machine-readable information relating to the moieties wherein the information is physically associated with the substrate (citing column 42, lines 46-67, and FIGS. 26 and 27). Other aspects of Nova have been cited for the disclosure of various elements of the pending dependent claims. While Nova is

acknowledged to be silent regarding a source of the target, Virtanen has nonetheless been relied upon to suggest the inclusion of a target moiety source.

Applicants respectfully submit that the Office Action fails to set forth a proper basis for rejection of the claims under 35 U.S.C. §103 since each and every element of the claims is not disclosed by Nova or the combination of Nova and Virtanen.

As noted above, amended independent claim 1 recites that the "target moiety is a substance that induces a detectable response signal by the probe moieties and interaction between the target moiety and a probe moiety results in the detectable response signal from the site of the probe moiety interacting with the target moiety." Like Virtanen, Nova fails to disclose or suggest such a feature to support a §103 rejection.

More specifically, Nova describes a number of possibilities in which moieties may be attached to a substrate and certain detection techniques may be used to detect the binding of the attached moiety to a ligand, molecule or biological particle. For example, the use of fluophors or scintillants to detect such binding is described by Nova (e.g., cols. 76-82 and other locations). However, the discussion provided by Nova does not evidently provide a disclosure of a target moiety "that induces a detectable response signal by the probe moieties and interaction between the target moiety and a probe moiety results in the detectable response signal from the site of the probe moiety interacting with the target moiety" according to applicants' claims.

By comparison, according to applicants' claims, the target moiety "induces a detectable response signal by the probe moieties." As noted, the term "induce" should be understood in terms of its ordinary meaning, namely that the target moiety "causes" or "produces" the response signal by attachment to the probe moiety, rather than simply preventing loss of the signal. For this reason, applicants submit that the device of claim 1 is different from and not suggested by the device described by Nova.

Applicants further respectfully submit that Virtanen fails to cure the deficiencies of Nova. In particular, inasmuch as both Virtanen and Nova do not disclose a device wherein the target moiety induces a detectable response signal by the probe moieties, it cannot be said that Virtanen somehow provides the requisite missing information that would suggest a modification of Nova according to applicants' claims. Indeed, since both references are missing this information, neither can cure this deficiency.

For at least the foregoing reasons, applicants request withdrawal of the rejection based on the combination of Nova and Virtanen.

Further Reasons for Patentability over the Applied References:

As noted above, claims 1-9, 11-27, 30-44, 91, 93-103, 107, and 108 have been rejected over Virtanen, the combination of Virtanen with Hammock and/or the combination of Nova with Virtanen. Of the pending claims, then, claims 28 and 29 have not been rejected over any of the applied references, either singly or as a combination of references. As may be noted, claims 28 and 29 are directed to the use of a protective (covering) layer that allows electromagnetic radiation to be transmitted through the protective layer. Accordingly, the Office position acknowledges that claims 28 and 29 are both novel and nonobvious over the art. As such, claims 28 and 29 are allowable even though they depend (indirectly) from claim 1. A notification indicating that claims 28 and 29 are allowable is respectfully requested.

Applicants also note that the features of claims 24 and 25 are further patentable over the applied references. Specifically, claim 24 recites that "the attached probe moieties are protected by a covering layer that covers the attached probe moieties" and claim 25 recites that this "protective layer encases the attached probe moieties." Each of Virtanen, Hammock and Nova fail to disclose or suggest such a feature. Although Nova has been cited in the Office Action as disclosing a "screen or mesh" (see page 16 of the Detailed Action regarding claims 24-26), such a feature does not function as a protective covering layer let alone a protective covering layer that encases the probe moieties. As further described by Nova at column 42, beginning at line 46 in reference to Figure 26, the disclosed mesh functions to retain particles but permits chemical materials and biological particles to pass through. In contrast, applicants' probe moieties are covered by a protective layer, not a mesh or screen according to Nova. While applicants' invention is not limited thereto, one embodiment of the invention that includes such a protective covering layer is schematically illustrated in Figure 3 (see layer 26 and the accompanying text in the specification beginning at page 22, line 10).

Accordingly, applicants submit that claim 24, as well as claims 25-29 that depend from claim 24, are allowable over Nova. A prompt notification that claims 24-29 are allowable is therefore respectfully requested.

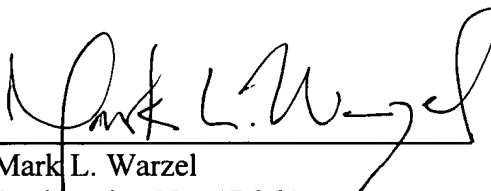
CONCLUSION

Accordingly, it is submitted that the pending claims define an invention that is patentable over the art. As the application should now be in condition for allowance, a prompt indication to that effect would be appreciated.

If the Examiner has any questions concerning this communication, a telephone call to the undersigned at (650) 330-0900 would be appreciated.

Respectfully submitted,

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